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July 8, 1999

The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53 156-0904, is making the following statements:

- (1) The antigenic properties promote healthy cellular division, function, and growth. \*
- (2) The bovine pancreas PMG<sup>TM</sup> extract in Pancreatrophin PMG appears to neutralize the circulating antibody, thereby contributing to the maintenance of cellular health.\*
- (3) Pancreatrophin PMG helps maintain a healthy gastrointestinal tract.\*
- (4) Pancreatrophin PMG sustains metabolic activity.\*
- (5) Maintains cellular health.\*
- (6) Chlorophyll protects and detoxifies the gastrointestinal tract and helps maintain healthy intestinal flora.\*
- (7) Nutritional yeast helps to support a healthy balance of normal intestinal flora. \*
- (8) Nutritional yeast is also a source of essential amino acids and enzymes that break down proteins. \*
- (9) Pancreatrophin PMG provides nutritional ingredients and support for the pancreas.\*

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STANDARD PROCESS INC. • 1200 WEST ROYAL LEE DRIVE • PALMYRA, WI 53156 • 414.495.2122 • FAX 414.495.2512 • 1.800.848.5061



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These statements are made for a dietary supplement containing a proprietary blend of magnesium citrate and bovine pituitary **PMG™** extract. Other ingredients include calcium lactate, **cellulose**, and calcium stearate. And the name of the product is Pituitrophin **PMG®**.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden  
Standard Process Inc.





These statements are made for a dietary supplement containing a proprietary blend bovine pancreas PMG™ extract, dried alfalfa juice, nutritional yeast, porcine duodenum, defatted wheat (germ), dried buckwheat (leaf) juice, and buckwheat (seed). Other ingredients include arabic acid and calcium stearate. The name of the product is Pancreatrophin PMG®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden  
Standard Process Inc.

